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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,777

02/26/2007

Alain Bernard

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EXAMINER

KOSAR, AARON J

ART UNIT

PAPER NUMBER

1651

NOTIFICATION DATE

DELIVERY MODE

03/03/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@lepatents.com

Office Action Summary	Application No. 10/580,777	Applicant(s) BERNARD ET AL.	
	Examiner AARON J. KOSAR	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/26/2006; 6/5/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on December 6, 2010 is acknowledged.

Claims 1-32 are pending of which claims 29-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 6, 2010.

Claims 1-28 are pending and have been examined on the merits.

Specification

The disclosure is objected to because of the following informalities:

On page 1 at line 23, the term "dis ks" appears to be an inadvertent typographical error of the term --disks--.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. (see e.g. page 2, at lines 6-7).

Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the claim recites that the method is a method of “recycling a solid support” for “cultivation of anchorage-dependent cells” which is “within a system for cell cultivation”; however, it is unclear if cells or a cell-cultured substrate are required of the method or if they are merely exemplary. Furthermore, the claim does not recite any required sequence or a conclusion of a recycled support and thus it is also unclear if the recited steps provide said recycled solid support or if another product of the method or another method is intended. Clarification is required.

In claim 1 at lines 4-6, the claim recites “rinsing” the system with “aqueous solution” (lines 4, 6) and with “sodium hydroxide solution”; however, it is unclear if the rinsing steps (b), (c), and/or (d) are intended to be the same rinsing step and solution (e.g. aqueous sodium hydroxide solution) or if different steps and/or solutions are intended. Clarification is required.

In claim 25 the claim recites the phrases “about 50°C to about 70 minutes” and “about 55°C to about 65°C minutes”; however, it is unclear if a temperature or temporal unit(s) are intended and one of skill would not be apprised as to what Applicant intends by the claims. Clarification is required.

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All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 USC § 112, second paragraph, for the reasons set forth above.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recycling a solid support for cultivation of a CHO anchorage-dependent cell, wherein the solid support comprises a polymer selected from polyester and polypropylene, does not reasonably provide enablement for all materials and all cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

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The claims are drawn to a method of recycling a solid support within a system for cultivation; however the specification discloses a method of treating a CHO cell-culturing substrate, the substrate comprising a polyester-polypropylene disk (referenced to the trademark Fibra-Cel®). Thus, the claims taken together with the specification imply a breadth which is greater than supported by the disclosure.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the prior art is such that culturing cells with a variety of supports and cells is known; however, the re-use/recycling of such supports/materials and the cells capable of cultivation thereupon was unresolved at the time of the instant invention, as taught by NBSC which teaches that one of skill that microcarriers and polymer disks (Fibra Cel®) should not be reused (NBSC, 2003, see entire document e.g. page 7).

Since the determination of recycling methods for anchorage-dependent cell substrates and the cells subsequently cultivatable thereupon remains largely unsolved, means for providing said recycling and for said cells is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high; however, with regards to recycling support materials in cell-cultivation methods as instantly claimed is beyond the purview of the skilled artisan. Accordingly, one of skill would turn to the instant disclosure for further guidance.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided a single CHO cell and a single substrate comprising a disk of polyester non-woven fibre bonded to a sheet of polypropylene mesh (Fibra-Cel®). However,

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the specification does not provide additional methods reusing other materials or cells except for those specifically exemplified. The specification does not teach working examples of additional substrates or additional cells which would function in the manner claimed nor does the specification provide the minimal structure(s) or interaction(s) by which one would determine a cell and/or substrate as being cultivatable on the substrate or the recycled substrate in an anchorage-dependent manner.

(8) The quantity of experimentation necessary:

Considering the state of the art and as discussed by NBSC and the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in scope with the instant claims.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/
Examiner, Art Unit 1651

/Christopher R. Tate/
Primary Examiner, Art Unit 1655